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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/641,396	08/17/2000	Mikhail F. Gordeev	6270.N DVI	7157

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Pharmacia & Upjohn Company
Global Intellectual Property
301 Henrietta Street
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EXAMINER

BAKER, MAURIE GARCIA

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 09/25/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary

Application No.
09/641,396

Applicant(s)
Gordeev et al

Examiner
Maurie G. Baker, Ph.D.

Art Unit
1639



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 8, 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 101-113 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 101-113 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Aug 17, 2000 is/are a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

1. The Response filed July 8, 2003 (Paper No. 15) is acknowledged. Claims 44-48 were cancelled and claims 101-113 were added. Therefore, claims 101-113 are pending and under examination in this action.

Status of Rejections

2. Some of the previous rejections under 35 U.S.C. 112 are maintained but are rewritten in light of the claim amendments (filing of new claims). Responses to applicant's arguments, as they pertain to the newly filed claims, are set forth following each maintained rejection. Any rejection not repeated in this action has been withdrawn in view of applicant's claim amendments. New rejections are also set forth below. As these new rejections were not entirely necessitated by applicant's claim amendments, the case remains in non-final status.

Drawings

3. The drawings are objected to by the draftsman under 37 C.F.R. 1.84 or 1.52. See PTO-948 attached to this action for the details of these objections. Note that the specification may require revision to correspond with drawing changes. *Please note the following new policy with respect to drawing changes, especially with respect to Timing of Corrections.*

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

Maintained Rejections *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 101-103, 105 and 107-113 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for carrying out the claimed process under the following conditions: (1) where the azide of the aryl oxazolidinone starting compound is converted to an iminophosphorane (upon treating with Ph_3P) and (2) this starting material is attached to a carbonyl containing resin by reaction of the

iminophosphorane with the resin; does not reasonably provide enablement for the method of preparing combinatorial libraries of compounds of the formula 1b using aryl oxazolidinone starting compounds attached to a resin at *any* attachment point and by *any* method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

It is clear from applicant's specification how one might practice this invention under the following conditions: (1) where the azide of the aryl oxazolidinone starting compound is converted to an iminophosphorane (upon treating with Ph_3P) and (2) this starting material is attached to a carbonyl containing resin by reaction of the iminophosphorane with the resin; however, there is insufficient guidance as to how to carry out the claimed method of preparing combinatorial libraries of compounds of the formula 1b using aryl oxazolidinone starting compounds attached to a resin at *any* attachment point and by *any* method. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include, but are not limited to:

- (1) the breadth of the claims;
- (2) the nature of the invention;
- (3) the state of the prior art;
- (4) the level of one of ordinary skill;
- (5) the level of predictability in the art;
- (6) the amount of direction provided by the inventor;
- (7) the existence of working examples; and

- (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The breadth of the claims and the nature of the invention: Applicant's claims are directed to a method of preparing combinatorial libraries of compounds of the formula 1b; however, the library is made by "attaching a plurality of aryl oxazolidinones to a plurality of solid supports". Such represents broad scope. In claims 101 and 108-113, no specifics on the attachment chemistry to the solid support is set forth whatsoever. It is noted that the dependent claims 102, 103, 105 and 107 do define *portions* of the attachment chemistry to the solid support. However, it is the examiner's position that only claims 104 and 106 recite enabled embodiments with the necessary specificity and thus the rest of the claims under examination (i.e. 101-103, 105 and 107-113) are included in this rejection. The state of the prior art and the level of predictability in the art: It is noted that the reaction site for attachment to the solid support of the claimed aryl oxazolidinone starting compound as well as the reactive group on the solid support are not set forth (i.e. in independent claim 101) and thus the level of predictability in the art for how to make and use such compounds in a solid phase synthesis scheme would be low. The structures of possible solid supports and reactions of the claimed starting material with such supports are sufficiently diverse that one of ordinary skill would not be able to predict them. The instant specification also gives no guidance to permit one of skill in the art to devise strategies for attaching the claimed aryl oxazolidinone starting compound to *any* solid support at *any* site.

Further research would be necessary to carry out the claimed invention since one of ordinary skill could not guess, *a priori*, how to make and use any such entities. The “predictability or lack thereof” in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. The level of one of ordinary skill: The level of skill would be high, most likely at the Ph.D. level. However, such persons of ordinary skill in this art, *given its unpredictability*, would have to engage in undue (non-routine) experimentation to carry out the invention as claimed. The amount of direction provided by the inventor and the existence of working examples: The examples in the instant specification only show the claimed reaction under the following conditions: (1) where the azide of the aryl oxazolidinone starting compound is converted to an iminophosphorane (upon treating with Ph_3P) and (2) this starting material is attached to a carbonyl containing resin by reaction of the iminophosphorane with the resin. See, for example, Figures 18 & 20 and page 31, line 14 through page 35, line 17 of the instant specification. That is, the attachment site to the resin is the azide and the reactive moiety on the solid support is carbonyl. The instant specification gives one skilled in the art no indication that one would have a reasonable expectation

of success of using any other reaction conditions in the solid phase synthesis scheme due to the unpredictability of the necessary chemistry. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved. See *In re Fisher*, 57 CCPA 1099, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). The quantity of experimentation needed to make or use the invention based on the content of the disclosure: The instant specification does not provide to one skilled in the art a reasonable amount of guidance with respect to the direction in which the experimentation should proceed in carrying out the full scope of the claimed method due to the deficiencies described above. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 & n.23 (Fed. Cir. 1991). Therefore, it is deemed that further research of an unpredictable nature would be necessary to make and/or use the invention as claimed. Thus, due to the inadequacies of the instant disclosure, one of ordinary skill would not have a reasonable expectation of success and the practice of the full scope of the invention would require undue experimentation.

Response to Arguments

6. Applicant's arguments filed July 8, 2003 have been fully considered but are not found persuasive. The examiner's rationale is set forth below.

7. Applicant argues that the "azide can be reacted with a variety of functional groups on the resin" (Response, page 5). While this may be true, the examiner's position is that such reactions would be unpredictable in light of the below. As stated in the rejection, the reaction site for attachment to the solid support of the claimed aryl oxazolidinone starting compound as well as the reactive group on the solid support are not set forth (i.e. in independent claim 101) and thus the level of predictability in the art for how to make and use such compounds in a solid phase synthesis scheme would be low. Also, the examples in the instant specification only show the claimed reaction under the conditions where the azide of the aryl oxazolidinone starting compound is converted to an iminophosphorane (upon treating with Ph_3P) and this starting material is attached to a carbonyl containing resin by reaction of the iminophosphorane with the resin. Thus, the instant specification does not provide to one skilled in the art a reasonable amount of guidance and further research of an unpredictable nature would be necessary to make and/or use the invention as claimed.

8. It is noted that although the reaction of the azide of the aryl oxazolidinone starting compound to form an amine and subsequent attachment to a carbonyl containing resin is

not specifically exemplified, since such chemistry would be within the knowledge of one of ordinary skill in the art, claim 106 is also **not** included in the above rejection.

9. Again, it is specifically noted that there is nothing in the current independent claim that indicates that the azide is the site for attachment of the aryl oxazolidinone starting compound to the solid support or what the reactive group is on the solid supports. For these reasons, the rejection under 35 U.S.C. 112, first paragraph is maintained.

Maintained & New Rejections
Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 101-103, 105 and 107-113 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. {maintained} Claims 101-103, 105 and 107-113 are indefinite as it is incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the reaction site for attachment to the solid support of the claimed aryl oxazolidinone starting compound as well as the reactive group on the solid support. Thus, one of ordinary skill would not know the metes and bounds of the claimed invention.

See also rejection under 112, first paragraph above. This deficiency brings about confusion as it is unclear how and where compounds are attached to the solid support (linkage site and linkage chemistry).

B. {new} There is insufficient antecedent basis in claim 107 for the term “imine”. Note that claim 107 depends from claim 102, which appears to be an error and is confusing as there is nothing in claim 102 with respect to imines.

C. {new} There is insufficient antecedent basis in claim 113 for the term “-CH₂NR₁₂R₁₃” (emphasis added). Note that claim 113 ultimately depends from claim 101, which recites this group as “-CH₂NR₁₈R₁₉” (emphasis added).

Response to Arguments

12. Applicant's arguments filed July 8, 2003 have been fully considered but are not found persuasive. The examiner's rationale is set forth below.

13. Applicant merely argues that since the newly filed claims (1) recite specific starting material aryl oxazolidinones (i.e. azides) and (2) require specific the chemical functionalization to produce R₁, that the claims are definite. Although the examiner agrees that the claims are now definite with respect to the chemical functionalization to produce R₁, the claims remain unclear as to the reaction site for attachment to the solid support of the claimed aryl oxazolidinone starting compounds as well as the reactive group on the solid support. These moieties are simply not set forth, amounting to a gap

between the necessary structural relationships. See also paragraphs 6-9 above. For these reasons, the rejection under 35 U.S.C. 112, second paragraph is maintained.

New Rejections
Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

15. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 101-113 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5 and 52 of U.S. Patent No. 6,441,005.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

The conflicting claims are not patentably distinct from each other because the claims of the patent are drawn to a method for solid phase synthesis of compounds that are within the scope of the instantly claimed compounds of the formula 1b. The portion of U.S. Patent No. 6,441,005 that supports this method of synthesis clearly reads on the method steps recited in the instant claims. Thus the examined claims would be anticipated by the reference claims.

17. Claims 101-113 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5 and 83 of copending Application No. 10/183,198 (Published as US 2002/0169191).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is

patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

The conflicting claims are not patentably distinct from each other because the claims of the patent are drawn to a method for solid phase synthesis of compounds that are within the scope of the instantly claimed compounds of the formula 1b. The portion of copending Application No. 10/183,198 that supports this method of synthesis clearly reads on the method steps recited in the instant claims. Thus the examined claims would be anticipated by the reference claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.


Status of Claims/Conclusion

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner is on an increased flextime schedule but can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
September 17, 2003



MAURIE GARCIA BAKER PH.D.
PRIMARY EXAMINER